



2-20-07

1626

Attorney's Docket No.: 20750-038US1 / 029.US2.PCT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Graeme Semple, et al.                      Art Unit : 1626  
Serial No. : 10/530,902                                      Examiner : Rebecca L. Anderson  
Filed : April 8, 2005                                        Conf. No. : 2895  
Title : 5-SUBSTITUTED 2H-PYRAZONE-3-CARBOXYLIC ACID DERIVATIVES AS  
ANTILIPOLYTIC AGENTS FOR THE TREATMENT OF METABOLIC-  
RELATED DISORDERS SUCH AS DYSLIPIDEMIA

**MAIL STOP AMENDMENT**

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INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

This statement is being filed within three months of the filing date of the application or before the receipt of a first Office Action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

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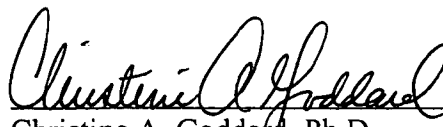
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Applicant : Graeme Semple, et al.  
Serial No. : 10/530,902  
Filed : April 8, 2005  
Page : 2 of 2

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Respectfully submitted,

Date: February 15, 2007

  
Christine A. Goddard, Ph.D.  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 6

**Complete if Known**

Application Number	10/530,902
Filing Date	April 8, 2005
First Named Inventor	Graeme Semple
Art Unit	1626
Examiner Name	Anderson, Rebecca L
Attorney Docket Number	29.US2.PCT

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication/Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
/K.S./	FL	US-2005/154024	07-14-2005	Bryans et al.,	
/K.S./	FM	US-2005/182108	08-18-2005	Carson et al.,	
/K.S./	FN	US-6,444,816 B1	09-03-2002	Das et al.,	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date/Filing Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/K.S./ ↓	FO	WO2003/032928 A1	04-22-2004	Arena Pharmaceuticals, Inc.		
	FP	WO2004/054974	07-01-2004	SmithKline Beecham Corporation		
	FQ	WO2005/009965	02-03-2005	Pfizer Ltd.		
	FR	WO2005/084663	09-15-2005	Janssen Pharmaceutica		
	FS	WO2006/023750	03-02-2006	Merck & Co., Inc.		
	FT	WO2006/032519	03-30-2006	Hoffmann-La Roche		
	FU	WO2006/032851	03-30-2006	Biolirop AB		
	FV	WO2006/032852	03-30-2006	Biolirop AB		
	FW	WO2006/052569	05-18-2006	Arena Pharmaceuticals, Inc.		
	FX	WO02/22601	03-21-2002	Vertex Pharmaceuticals, Inc.		
	FY	WO00/69849	11-23-2000	Ortho-McNeil Pharmaceutical, Inc.		
	FZ	WO03/099793	12-04-2003	Takeda Chemical Industries, Ltd.		
	GA	WO2004/033431	04-22-2004	Arena Pharmaceuticals, Inc.		
	GB	GB 1048104	11-09-1966	The Upjohn Company		
	GC	JP 54014968	02-03-1979	Taiho Pharmaceutical Co. Ltd.		
/K.S./	GD	HU184940B	11-28-1984	Gyogyszerkutato Intezet		

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 6

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Application Number	10/530,902
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First Named Inventor	Graeme Semple
Art Unit	1626
Examiner Name	Anderson, Rebecca L
Attorney Docket Number	29.US2.PCT

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/K.S./	GE	FROESCH <i>et al.</i> , Effects of 5-methylpyrazole-3-carboxylic acid on adipose tissue. I. Inhibition of lipolysis, effects on glucose, fructose, and glycogen metabolism in vitro and comparison with insulin. <i>Molecular Pharmacol.</i> (1967), 3(5), 429-41	
	GF	MUGNAINI <i>et al.</i> Heterocyclic syntheses with propargyl alcohol and butynediol. II. <i>Classe sci. fis., mat. e nat.</i> (1953), 14, 275-80	
	GG	MUGNAINI <i>et al.</i> Heterocyclic syntheses with propargyl alcohol and butynediol. <i>Classe sci. fis., mat. e nat.</i> (1953), 14, 95-8	
	GH	HÜTTEL Über einige Aldehyde der Pyrazol- und der 1.2.3-Triazol-Reihe. <i>Berichte der deutschen chemischen Gesellschaft (A and B Series)</i> 74(10), 1941,1680-1687	
	GI	PANIZZI <i>et al.</i> Heterocyclic syntheses. VII. Some pyrazolic ketones. <i>Gazzetta Chimica Italiana</i> (1946), 76, 66-77	
	GJ	MELANI <i>et al.</i> Synthesis of 5H-10,11-dihydropyrazolo[5,1-c][1,4]benzodiazepine derivatives. II. <i>Journal of Heterocyclic Chemistry</i> (1984), 21(3), 813-15	
	GK	KLAGES <i>et al.</i> Pyrazoles from 1:3-diketones and alkyl diazoacetates. <i>Journal fuer Praktische Chemie</i> (1902), 65(ii), 387-93	
	GL	OWEN <i>et al.</i> Olefinic acids. II. Reactivity of $\alpha$ -bromoacrylic acid and some related compounds. <i>Journal of the Chemical Society</i> (1947), 1030-4	
	GM	ABDALLAH <i>et al.</i> Diazoacetaldehyde dimethyl acetal: a new route to cyclopropane aldehydes and formylpyrazoles. <i>Tetrahedron Letters</i> (1980), 21(23), 2239-42	
	GN	International Search Report, WO 2005/011677, 12/10/2004	
	GO	ALTSCHUL <i>et al.</i> Influence of nicotinic acid on serum cholesterol in man. <i>Archives of biochemistry</i> (1955), 54(2), 558-9	
	GP	TAVINTHARAN <i>et al.</i> The benefits of niacin in atherosclerosis. <i>Current atherosclerosis reports</i> (2001), 3(1), 74-82	
/K.S./	GQ	CARLSON <i>et al.</i> Nicotinic acid: the broad-spectrum lipid drug. A 50th anniversary review. <i>Journal of Internal Medicine</i> (2005), 258(2), 94-114	

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Sheet 3 of 6

### Complete if Known

Application Number	10/530,902
Filing Date	April 8, 2005
First Named Inventor	Graeme Semple
Art Unit	1626
Examiner Name	Anderson, Rebecca L
Attorney Docket Number	29.US2.PCT

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/K.S./	GR	LORENZEN <i>et al.</i> Characterization of a G protein-coupled receptor for nicotinic acid. <i>Molecular Pharmacology</i> (2001), 59(2), 349-357	
	GS	SOGA <i>et al.</i> Molecular identification of nicotinic acid receptor. <i>Biochemical and Biophysical Research Communications</i> (2003), 303(1), 364-369	
	GT	TUNARU <i>et al.</i> PUMA-G and HM74 are receptors for nicotinic acid and mediate its anti-lipolytic effect. <i>Nature Medicine</i> (2003), 9(3), 352-355	
	GU	ZHANG <i>et al.</i> , Niacin mediates lipolysis in adipose tissue through its G-protein coupled receptor HM74A. <i>Biochemical and Biophysical Research Communications</i> (2005), 334(2), 729-732	
	GV	BENYO <i>et al.</i> GPR109A (PUMA-G/HM74A) mediates nicotinic acid-induced flushing. <i>Journal of Clinical Investigation</i> (2005), 115(12), 3634-3640	
	GW	O'KANE <i>et al.</i> A comparison of acipimox and nicotinic acid in type 2b hyperlipidaemia. <i>British journal of clinical pharmacology</i> (1992), 33(4), 451-3	
	GX	JIRKOVSKY <i>et al.</i> , Hypolipidemic 4,5-dihydro-4-oxo-5,5-disubstituted-2-furancarboxylic acids. <i>Journal of Medicinal Chemistry</i> (1982), 25(10), 1154-6	
	GY	HUNNINGHAKE <i>et al.</i> Controlled trial of acifran in type II hyperlipoproteinemia. <i>Clinical pharmacology and therapeutics</i> (1985), 38(3), 313-7	
	GZ	SEKI <i>et al.</i> , Studies on hypolipidemic agents. II. Synthesis and pharmacological properties of alkylpyrazole derivatives. <i>Chemical &amp; Pharmaceutical Bulletin</i> (1984), 32(4), 1568-77	
	HA	VAN HERK <i>et al.</i> , Pyrazole Derivatives as Partial Agonists for the Nicotinic Acid Receptor. <i>Journal of Medicinal Chemistry</i> (2003), 46(18), 3945-3951	
	HB	MAHBOUBI <i>et al.</i> , Triglyceride modulation by acifran analogs: activity towards the niacin high and low affinity G protein-coupled receptors HM74A and HM74. <i>Biochemical and Biophysical Research Communications</i> (2006), 340(2), 482-490	
	HC	FROESCH <i>et al.</i> , Effects of 5-methylpyrazole-3-carboxylic acid on adipose tissue. II. Antilipolytic and hypoglycemic effects in vivo. <i>Molecular Pharmacol.</i> (1967), 3(5), 442-52	
	HD	Beilstein Records (BRN): 10958, Chemical Name (CN): 4-methyl-5-propionyl-1(2) <i>H</i> -pyrazole-3-carboxylic acid	
/K.S./	HE	Beilstein Records (BRN): 14055, Chemical Name (CN): 4-methyl-5-propionyl-1(2) <i>H</i> -pyrazole-3-carboxylic acid ethyl ester	

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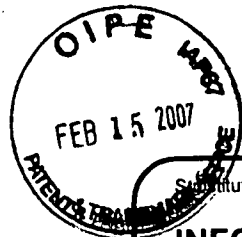
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Sheet 4 of 6

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Application Number	10/530,902
Filing Date	April 8, 2005
First Named Inventor	Graeme Semple
Art Unit	1626
Examiner Name	Anderson, Rebecca L
Attorney Docket Number	29.US2.PCT

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/K.S./	HF	GERRITSEN <i>et al.</i> , Effects of 5-methylpyrazole-3-carboxylic acid, U-19425, on FFA [free fatty acid] mobilization. <i>Advan. Exp. Med. Biol.</i> (1969), 4 93-103	
	HG	BIZZI <i>et al.</i> , Correlation between the effect of drugs on plasma free fatty acids and on tissue triglycerides. <i>Advan. Exp. Med. Biol.</i> (1969), 4 201-11	
	HH	GUNDERSEN <i>et al.</i> , Effects of 5-methylpyrazole-3-carboxylic and (U-19,425) and nicotinic acid (NA) on free fatty acids (FFA), triglycerides (TG), and cholesterol in man. <i>Advan. Exp. Med. Biol.</i> (1969), 4, 213-26	
	HI	KIENER, Enzymic oxidation of methyl groups in heteroarenes: a versatile method for the preparation of heteroaromatic carboxylic acids. <i>Angew. Chem., Int. Ed. Engl.</i> , 1992, 31(6), 774-5	
	HJ	AKTORIES <i>et al.</i> , Inhibition of adenylate cyclase and stimulation of a high affinity GTPase by the antilipolytic agents, nicotinic acid, acipimox and various related compounds. <i>Arzneimittel-Forschung</i> (1983), 33(11), 1525-7	
	HK	PRYOR <i>et al.</i> , Purification of maize alcohol dehydrogenase and competitive inhibition by pyrazoles. <i>Biochemistry International</i> (1982), 4(4), 431-8	
	HL	BIZZI <i>et al.</i> , Effects of antilipolytic agents on glucose utilization by adipose tissue. <i>Biochemical Pharmacology</i> (1973), 22(6), 763-8	
	HM	MYLES <i>et al.</i> , The development of tolerance to antilipolytic agents in rats. <i>Biochemical Pharmacology</i> (1985), 34(2), 269-74	
	HN	STRATTON <i>et al.</i> , The development of tolerance to antilipolytic agents by isolated rat adipocytes. <i>Biochemical Pharmacology</i> (1985), 34(2), 275-9	
	HO	COTTINEAU <i>et al.</i> , Synthesis and hypoglycemic evaluation of substituted pyrazole-4-carboxylic acids. <i>Bioorganic &amp; Medicinal Chemistry Letters</i> (2002), 12(16), 2105-2108	
	HP	HAMILTON <i>et al.</i> , The inhibition of mammalian D-amino acid oxidase by metabolites and drugs. Inferences concerning physiological function. <i>Bioorganic Chemistry</i> (1982), 11(3), 350-70	
	HQ	ISSEKUTZ, Effect of nicotinic acid, 5-methylpyrazole-3-carboxylic acid (U-19425), and dibutylrly cyclic AMP on renal gluconeogenesis. <i>Canadian Journal of Physiology and Pharmacology</i> (1971), 49(2), 102-5	
	HR	REIMLINGER <i>et al.</i> , Syntheses with silver or sodium pyrazoles. II. Reactions of the silver salts of methylpyrazoles with halogens. <i>Chemische Berichte</i> (1970), 103(6), 1949-53	
	HS	SEKIHACHI <i>et al.</i> , Synthesis and chromophoric properties of symmetrical bis-heteroannellated diketopiperazines: diimidazo- and dipyrazolo-piperazinediones. <i>Dyes and Pigments</i> (1996), 32(1), 43-58	
/K.S./	HT	TIHANYI <i>et al.</i> , Pyrazolecarboxylic acid hydrazides as antiinflammatory agents. New selective lipoxygenase inhibitors. <i>European Journal of Medicinal Chemistry</i> (1984), 19(5), 433-9	

Examiner Signature	/Kamal Saeed/	Date Considered	03/30/2009
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/K.S./	HU	BARALDI <i>et al.</i> , Synthesis, antibacterial activity and structure-activity relationships of N-substituted 4-diazopyrazole-5-carboxamides. 2. <i>Farmaco</i> (1991), 46(11), 1337-50	
	HV	ALBERTI <i>et al.</i> , Alkylpyrazoles. <i>Farmaco, Edizione Scientifica</i> (1961), 16 527-39	
	HW	ALEMAGNA <i>et al.</i> , Pyrazole synthesis from $\alpha$ -dicarbonyl compounds. <i>Gazzetta Chimica Italiana</i> (1963), 93(6), 748-56	
	HX	INFANTES <i>et al.</i> , Packing modes in eight 3-ethoxycarbonylpyrazole derivatives. Influence of the substituents on the crystal structure and annular tautomerism. <i>Heterocycles</i> (1999), 50(1), 227-242	
	HY	BERINGER <i>et al.</i> , Attempts towards oral diabetes therapy by means of inhibition of lipolysis with 5-methylpyrazole-3-carboxylic acid. <i>Hormone and Metabolic Research</i> (1970), 2(2), 81-5	
	HZ	MISHRA <i>et al.</i> , A heteroaromatic acid from marine sponge <i>Suberites vestigium</i> . <i>Indian Journal of Chemistry, Section B: Organic Chemistry Including Medicinal Chemistry</i> (1998), 37B(2), 199-200	
	IA	BANKS, Selectfluor reagent F-TEDA-BF <sub>4</sub> in action: tamed fluorine at your service. <i>Journal of Fluorine Chemistry</i> (1998), 87(1), 1-17	
	IB	MIETHCHEN <i>et al.</i> , Micelle-activated reactions. I. Micelle-activated iodination and partial dehalogenation of pyrazoles and 1,2,4-triazoles. <i>Journal fuer Praktische Chemie</i> (Leipzig) (1989), 331(5), 799-805	
	IC	SAHA <i>et al.</i> , Mixed-ligand complexes of cobalt(II) and nickel(II) with 1-hydroxymethyl-5(3)-methylpyrazole-3(5)-carboxylic acid and heterocyclic amines. <i>Journal of the Indian Chemical Society</i> (1985), 62(2), 96-9	
	ID	SAHA <i>et al.</i> , Synthesis, characterization and coordinating properties of a new benzimidazolopyrazole: cobalt(II), nickel(II) and copper(II) complexes of 5-methyl-3-(2'-benzimidazolyl)pyrazole. <i>Journal of the Indian Chemical Society</i> (1993), 70(11-12), 1035-42	
	IE	PARAMESWARAN <i>et al.</i> , Secondary metabolites from the sponge <i>Tedania anhelans</i> : isolation and characterization of two novel pyrazole acids and other metabolites. <i>Journal of Natural Products</i> (1997), 60(8), 802-803	
	IF	MANAEV <i>et al.</i> , Dimethylpyrazole-based syntheses. V. Nitration of 4-halopyrazole-3- and 5-carboxylic acids. <i>Zhurnal Obshchei Khimii</i> (1982), 52(11), 2592-8	
/K.S./	IG	AKTORIES <i>et al.</i> , Stimulation of a low Km GTPase by inhibitors of adipocyte adenylate cyclase. <i>Molecular Pharmacology</i> (1982), 21(2), 336-42	

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/Kamal Saeed/

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Sheet 6 of 6

**Complete if Known**

Application Number	10/530,902
Filing Date	April 8, 2005
First Named Inventor	Graeme Semple
Art Unit	1626
Examiner Name	Anderson, Rebecca L
Attorney Docket Number	29.US2.PCT

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/K.S./	IH	AKTORIES <i>et al.</i> , In vivo and in vitro desensitization of nicotinic acid-induced adipocyte adenylate cyclase inhibition. <i>Naunyn-Schmiedeberg's Archives of Pharmacology</i> (1982), 318(3), 241-5	
	II	FRANCESCHI <i>et al.</i> , Synthesis and aggregation of two-headed surfactants bearing amino acid moieties. <i>New Journal of Chemistry</i> (1999), 23(4), 447-452	
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	IK	TAKASAKI <i>et al.</i> , Hypoglycemic activity of certain heterocyclic acid derivatives. <i>Nippon Yakurigaku Zasshi</i> (1973), 69(6), 977-94	
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	IS	BARIANA <i>et al.</i> , Nicotinic acid esters as coronary vasodilators. <i>Journal of Medicinal Chemistry</i> (1971), 14(4), 372-3	
/K.S./	IT	HOLLAND <i>et al.</i> , Heterocyclic tetrazoles, a new class of lipolysis inhibitors. <i>Journal of Medicinal Chemistry</i> (1967), 10(2), 149-54	

Examiner Signature	/Kamal Saeed/	Date Considered	03/30/2009
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